

Application No. 10/717,932
Reply dated November 1, 2004
Response to Office Action dated August 31, 2004

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-5 and 8-26 in view of the foregoing amendments and the following remarks.

I. Restriction Requirement

This Response is filed in reply to the Restriction Requirement mailed by the Patent and Trademark Office on August 31, 2004. The Restriction Requirement separates claims 1-26 twelve different ways (into Groups I-XII). In response to that requirement, the claims have been amended to reflect that A represents O, instead of O or S. This amendment is made without prejudice to the right to pursue claims in which A is sulfur in one or more separate divisional applications, and this right is expressly reserved. Responsive to the Restriction Requirement, provisional election to the Group wherein R1 may be a substituted phenyl radical and R2 may be $-(C=O)-$ phenyl, namely Group I, is made, with traverse.

The restriction requirement is improper because: (A) it fails to follow the rules of practice for Markush-type claims; (B) it contravenes the Applicants' statutory right to claim what they regard as their invention and (C) the reasoning offered in support of the restriction is not applicable to the presently-pending claims.

A. Failure to Follow Practice Regarding Markush-Type Claims

The Manual of Patent Examining Procedure (the "MPEP"), 8th Edition, U.S. Department of Commerce, Patent and Trademark Office, August 2001, sets forth the rules of practice related to the restriction of claims involving Markush groups. See § 803.02. In relevant part, the MPEP indicates that "[i]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless

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the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.” The presently pending claims clearly meet the test for unity of invention since (1) all of the compounds have medicinal properties and therefore have a common utility in medicinal applications and (2) all of the compounds share a common base structure wherein A represents oxygen in a furan moiety. The compounds share a substantial structural feature which is disclosed as being essential to the utility in that the provided compounds share a high affinity to binding site 2 of the sodium channel (the BTX binding site). Therefore, these claims share unity of invention and should be examined as written, without any restriction. Further, these rules relating to unity of invention reflect the practice that compounds must be considered as a whole, and not may not be improperly broken down into elements or other components.

The remainder of § 803.02 of the MPEP relates the proper procedure for Examining claims containing Markush groupings which include a plurality of alternatively usable substances or members. The procedures described include requiring a provisional election of species and examining the elected species. If no prior art is found that anticipates or renders obvious the elected species, the search for the Markush claim is extended to the non-elected species to determine patentability of the claim. Thus, even where claims have alternatively usable substances or members, the Markush groupings are examined until one of the groups is determined anticipated or obvious. In the absence of suitable prior art, the claim is allowable. The definitions provided for R1 and R2 are proper Markush groups and the examination of these claims should be in accordance with the guidance provided by the MPEP for examination of Markush groups.

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Thus, not only are Applicants entitled to examination of the presently pending claims because they share a common unity of invention, even for claims with alternatively usable substances or members, the proper practice for examination of Markush groupings is to examine the claims following the guidance provided by an election of species. Thus, the restriction requirement is improper and should be withdrawn.

B. Contravention of Statutory Provisions

By attempting to restrict the invention within the scope of a single independent claim, the attempted restriction contravenes the applicants' statutory right to claim what they regard as their invention. The language of the Court of Customs and Patent Appeals in *In re Weber*, 198 USPQ 328, 331 (CCPA 1978) sets forth applicants' statutory right as follows:

An applicant is given, by the statute, the right to claim his invention with the limitations he regards as necessary to circumscribe that invention, with the proviso that the application comply with the requirements of §112. We have decided in the past that §112, second paragraph, which says in part "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention," allows the inventor to claim the invention as he contemplates it. *In re Wolfrum*, 486 F.2d 588, 179 USPQ 620 (CCPA 1973).

As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be

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the equivalent of the original claim. Further, since the subgenera would be defined by the Examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. (emphasis in original).

Thus, the court made clear that the Applicant has a right to have each of the claims examined on the merits. Because the Examiner's restriction cuts across several of the claims, the proposed groups would contravene the Applicant's right to have each claim examined, and would, in effect, absolutely preclude the Applicant's original claim from being considered on its merits. Thus, the restriction requirement denies the applicant the rights to which they are statutorily entitled. This is precisely the type of denigration of applicant's statutory right which the law does not permit.

C. Reasoning Offered In Support of the Restriction is No Longer Applicable.

The Office Action asserts that the furan and thiophenes represent distinct art areas. In view of the presently pending claims, this reasoning is not applicable. The presently pending claims include only the furan base structure. Accordingly any distinction between inventions on this basis is no longer applicable.

The Office Actions also asserts that the heterocyclyl values of R1 and R6 render the claims broad. As amended, there is no longer any R6 group and R1 is limited to one of three different primary structures. Thus, only a discreet set of compounds are contemplated by the claims. Moreover, the relevant inquiry for purposes of a restriction is not the breadth of the claims, rather it is whether independent and distinct inventions are claimed in the same application.

Similarly, R2 is now limited to one of only two different primary structures, and accordingly a discreet set of compounds are contemplated by the claims.

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Finally, the Office Action indicates that the many provisos in the claims make it "obvious that there is much art that is very close." There are no provisos in the presently pending claims. Accordingly, this reasoning is no longer applicable.

II. Election of Species

For purposes of responding to the election of species requirement, 5-[1-(2-chloro-phenylamino)-2-oxo-2-phenyl-ethyl]-2-methyl-furan-3-carboxylic acid ethyl ester is elected.

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CONCLUSION

Accordingly, for all of the reasons noted above, reconsideration and withdrawal of the requirement for restriction, as it would relate to the presently pending claims, are respectfully requested.

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this response or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Attorney Docket No. 02931052907US).

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Respectfully submitted,



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